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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/598,982	06/21/00	MAFFITT	M 34506.104
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HM12/0921

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EXAMINER

RAMIREZ, D

ART UNIT	PAPER NUMBER
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1652
DATE MAILED: 09/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/598,982	Applicant(s) MAFFITT ET AL.
Examiner Delia M. Ramirez	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-61 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims 1-61 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) Interview Summary (PTO-413) Paper No(s). _____
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-25, 34-37, 41-45, 54-58, drawn to DNA constructs, host cells encoding and expression of recombinant human tryptases according to SEQ ID NO: 8, 10, 20, 22, 24, 26, 36, 38, 40, and 42, classified in class 536, subclass 23.2.
- II. Claims 40, 59-61, drawn to recombinant human tryptases according to SEQ ID NO: 9, 11, 21, 23, 25, 27, 37, 39, 41, and 43, classified in class 435, subclass 226.
- III. Claims 38-39, drawn to antibodies against human tryptases and a method of generating said antibodies, classified in class 530, subclass 387.1.
- IV. Claims 26-32, 46-52, drawn to a method of screening a library with recombinant human tryptases, classified in class 435, subclass 23.
- V. Claims 33, 53, drawn to a method for modeling recombinant human tryptases, classified in class 702, subclass 19.

The inventions are distinct, each from the other because of the following reasons:

Groups I, II, and III each comprise a chemically unrelated structure capable of separate manufacture, use, and effect. The DNA in Group I comprises a nucleic acid sequence, whereas the proteins of Group II and III each comprise an unrelated amino acid sequence. The DNA has other uses besides encoding the protein of Group II, such as a hybridization probe or in gene therapy. The protein from Group II can be used in materially different methods other than to make the antibody of Group III, such as in therapeutic or diagnostic methods (e.g. in

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screening). Further, the proteins of Group II and III can be prepared by processes which are materially different from recombinant DNA expression of Group I, such as by chemical synthesis, or by isolation and purification from natural sources.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Invention II can be used to make the antibodies of Invention III.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the proteins of Invention II are neither used nor made by the method of Invention V.

Inventions I, III and IV, or V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the DNA constructs of Invention I and the antibodies of Invention III are neither used nor made by the methods of Inventions IV or V. In addition the method for generating antibodies of Invention III comprises different steps, utilize different products, and produce different results to those of Inventions IV or V.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

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functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions IV and V comprise different steps, utilize different products, and produce different results.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper .

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
September 18, 2001



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